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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
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		10/725,890	DECEMBER 2, 2003
		First Named Inventor	
		STEVEN E. WALAK	
Art Unit		Examiner	
3767		BRADLEY JAMES OSINSKI	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. <input checked="" type="checkbox"/></p> <p>This request is being filed with a notice of appeal. <input checked="" type="checkbox"/></p> <p>The review is requested for the reason(s) stated on the attached sheet(s). <input checked="" type="checkbox"/> Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>41,376</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			

  
Signature

J. SCOT WICKHEM

Typed or printed name

612.677.9050

Telephone number

June 18, 2008

Date

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**P A T E N T**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	STEVEN E. WALAK	Confirmation No.:	3380
Serial No.:	10/725,890	Examiner:	Bradley J. Osinski
Filing Date:	DECEMBER 2, 2003	Group Art Unit:	3709
Docket No.:	1001.1632101	Customer No.:	28075
Title:	COMPOSITE MEDICAL DEVICE AND METHOD OF FORMING		

**PRE-APPEAL CONFERENCE BRIEF**

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\_\_\_\_\_  
Thu H. Le-To

\_\_\_\_\_  
JUNE 18, 2008

\_\_\_\_\_  
Date

Dear Sir:

Appellants have carefully reviewed the Final Office Action dated January 31, 2008 and the Advisory Action dated April 21, 2008. Currently, claims 1-22, 25-70 and 73-75 are pending in the application, claims 28-56 have been withdrawn from consideration, and the Examiner has rejected claims 1-22, 25-27, 57-70 and 73. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1-9, 11, 13, 15, 16, 18-21, 25-26, 57, 59, 61, 63-64, 66-68 and 73 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ren et al., U.S. Patent No. 6,045,547 (hereinafter "Ren") in view of Viera, U.S. Patent No. 6,039,699. However all the elements of these claims are neither disclosed by nor obvious over these references. As such, these claims are believed to be in condition for allowance.

For example, claim 1 recites “constructing a composite elongate shaft by forming a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein.” The structure of this claim element is disclosed by neither reference.

Ren is directed towards catheters made of polymer layers, with the possible inclusion of a wire braid or helix as a stiffening member. Viera is directed to a solid metallic core wire that may have a metallic sleeve disposed thereon. Significantly, this sleeve is formed separately and then secured to the core wire by an adhesive, welding, brazing or soldering. Viera, col. 4, ll. 26-29.

The mere substitution of the metallic materials of Ren, with the joining methods taught by Ren of adhesive, welding, brazing or soldering, would not produce the claimed structure. Constructing a shaft by forming the metallic outer portion about a metallic inner portion creates a composite shaft of unitary construction. See the specification at page 8, lines 23-29. In essence there is a metallic bond between the two layers running the length of the shaft. This metallic composite shaft of two distinct layers is a structural element that is not disclosed in either reference.

“The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product.” MPEP 2113 citing *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). In the present case, there is a structural element of the claims not taught by the prior art, and the Examiner must show why it is a non-obvious difference over the cited art. This has not been done.

In the advisory action, the Examiner points to the polymer extruding process taught by Ren and argues that “one of ordinary skill in the art looking to apply the co-extrusion method of Ren et al to metals would appreciate the difference and would still be able to successfully create the invention as claimed and that any structural difference would be non-existent.”

This argument is erroneous in two respects; it assumes the wrong questions and it conflates polymeric co-extrusion processes with metallic co-extrusion processes. As an initial

matter, one of skill in the art is not looking to apply the co-extrusion method of Ren to metals; one of skill in the art is looking to make the catheter of Ren out of metals as taught by Viera. Once the person of skill in the art decides it is advantageous to make the catheter of Ren out of metals as taught by Viera, that person of skill in the art would look to the metal fastening techniques as taught by Viera rather than the polymer techniques of Ren to create the catheter. There is no suggestion that the polymeric co-extrusion process of Ren is desirable or even possible with metallic materials.

As an analogy, consider a building made of bricks. Mortar is the preferred and perhaps very nearly the exclusive fastening means for building such a structure. It would nevertheless be obvious to make the same structure out of wood. When changing the material, one would not retain the mortar; one would switch to a fastening method more suiting to wood such as nails, screw or glue. To argue that one of ordinary skill in the art would even look to the co-extrusion means of Ren when making the catheter out of metal is impermissible hindsight.

Polymeric extrusion and metallic extrusion are two distinct techniques that use different tooling, operate at significantly different temperatures and pressures, and have different applications. For example, in metal extrusion, it is not known to produce a smoothly tapered end transition such as shown with element 31 of Figure 3 of Ren. Appellants understand that wetting effects and the viscosity of the molten metal make such a tapered transition effectively impossible. One may vary the thickness of extruded metal layers but appellants do not believe that such a long smooth taper to nothing as shown in Ren is practically possible with metal extrusion.

Therefore, one making the catheter of Ren out of the metallic materials of Viera would not use or modify the co-extrusion process of Ren. This method of manufacture is not an obvious one because there is no reasonable expectation of success when employing such a method. The Examiner has not shown that a catheter such as that of Ren could be made of metal by using a co-extrusion process.

Because all claim elements are not explicitly nor inherently disclosed by the cited references and because there is no reasonable expectation of success when modifying the

references as suggested by the Examiner, appellants respectfully submit that no prima facie case of obviousness has been made.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

STEVEN E. WALAK

By his attorney,

Date:

June 18, 2008



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